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10/814,160	04/01/2004	David Wallach	WALLACH=26A	7382

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,160	WALLACH ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-23 are pending in the application and are currently subject to restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-17 and 27, drawn to a DNA molecule, an oligonucleotide complementary to at least part of said DNA molecule, a vector comprising said DNA molecule, a host cell comprising said vector, and a method for producing a polypeptide, said method comprising growing said host cell, classified, for example, in class 536, subclass 23.5, class 435, subclass 320.1, class 435, subclass 325, and class 435, subclass 69.1.

Group II. Claims 18-25, drawn to drawn to a polypeptide or a composition thereof, classified, for example, in class 530, subclass 350.

Group III. Claim 26, drawn to a ribozyme, classified, for example, in class 514, subclass 44.

Group IV. Claim 28, drawn to an antibody, classified, for example, in class 530, subclass 387.1.

Group V. Claim 29, drawn to an "immunoassay", classified, for example, in 435, subclass 7.1.

Group VI. Claim 30, drawn to a method of identifying caspase-8 interacting proteins, classified, for example, in class 435, subclass 29.

Group VII. Claim 31, drawn to a method of modulating caspase-8 activity, classified, for example, in class 435, subclass 212.

Group VIII. Claims 32 and 33, drawn to a method for modulating TNF receptor- or Fas-mediated effects in a cell and/or modulating the apoptosis of a cell, classified, for example, in class 435, subclass 375.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-IV are or include products, whereas the inventions of Groups I and V-VIII are or include processes.

The inventions of Group I and the inventions of Groups V-VIII are unrelated because the products of Group I are not specifically used or otherwise involved in the processes of Groups V-VIII.

The inventions of Group III and the inventions of Groups I and V-VIII are unrelated because the products of Group III are not specifically used or otherwise involved in the processes of Groups I and V-VIII.

The inventions of Group II and the inventions of Groups I, V, and VI are unrelated because the products of Group II are not specifically used or otherwise involved in the processes of Groups I, V, and VI.

The inventions of Group IV and the inventions of Groups I and VI-VIII are unrelated because the products of Group IV are not specifically used or otherwise involved in the processes of Groups I and VI-VIII.

The inventions of Group II and the inventions of Groups VII and VIII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the polypeptide can be used in a materially different process of using that product, such as the process of using the

polypeptide as an immunogen to elicit the production in an animal of an antibody that binds the polypeptide.

The inventions of Groups II and the inventions of Group VII or VIII have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter, and the search performed in examining claims drawn to a product is a different from the search performed in examining claims drawn to a process using that product. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of Group II would not suffice to provide adequate information regarding the merit of the claims of Group VII or VIII, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups II and the inventions of Groups VII or VIII, an examination of both would constitute a serious burden.

Since the inventions of Groups II and the inventions of Groups VII or VIII have been shown to be patentably distinct, and because the examination of both inventions could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

The inventions of Groups I-IV are patentably distinct for the following reasons:

The inventions of Group I are nucleic acid molecules, vectors comprising such nucleic acid molecules, host cells comprising such nucleic acid molecules, and method for using such host cells, whereas the inventions of Group II are polypeptides, the inventions of Group III are ribozymes, and the inventions of Group IV are antibodies.

Polypeptides and polynucleotides are chemically distinct products, since polypeptides are composed of polymers of amino acids, whereas polynucleotides are composed of polymers of nucleotides. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of

the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, a polypeptide can be produced by means, other than the recombinant means by which a polynucleotide encoding a polypeptide might be used to produce the polypeptide, since a polypeptide can be produced (or isolated) by biochemical means, including, for example, affinity chromatography. In addition, while the polynucleotide might encode the polypeptide, generally, it can also encode another polypeptide using the information provided by an alternative open reading frame; and furthermore, since a polynucleotide can be used as a probe in hybridization-based analyses, the information provided by a polynucleotide can be used isolate different polynucleotides encoding polypeptides, which have amino acid sequences that differ from the amino acid sequence encoded by the disclosed polynucleotide. Consequently, the disclosed relationship between a polynucleotide capable of encoding a polypeptide and the polypeptide is not exclusive, since either the claimed polynucleotide or the claimed polypeptide can also be related to other polynucleotides or polypeptides, which are materially and chemically different from the claimed inventions. Therefore, the inventions of Groups I and II are patentably distinct products.

The inventions of Groups I and II have acquired a separate status in the art, as evidenced by their different classifications, and the search performed in examining claims drawn to a polynucleotide is a different from the search performed in examining claims drawn to a polypeptide. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims directed to the inventions of Group I would not suffice to provide adequate information regarding the merit of the claims directed to the inventions of Group II, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Group I and the inventions of Group II, an

examination of both would constitute a serious burden. Moreover, because the disclosed relationship between the polynucleotide and the polypeptide encoded by the polynucleotide is not absolute or exclusive of other relationships with different polynucleotides or polypeptides, the search of either group will likely provide information that is relevant to one but not the other; and as such, searching one in addition to the other would be unduly burdensome.

Since the inventions of Groups I and II are patentably distinct, and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

Furthermore, an antibody, such as an immunoglobulin G (IgG) molecule, typically comprises four polypeptides: two light chains and two heavy chains, each containing constant and variable regions, which interact with one another to form an antigen-binding domain comprised of amino acid residues in each chain. In contrast, the claimed polypeptides are disclosed as consisting of a single polypeptide chain; so the inventions of Groups II and IV are structurally distinct from one another. Thus, any relationship between an antibody and a polypeptide to which the antibody binds is codependent upon the structural (i.e., antigenic) information provided by the polypeptide, which is recognized as the antigenic determinant to which the antibody binds, and the selective binding nature of the antigen-binding domain of the antibody. However, a polypeptide comprises multiple antigenic determinants and can thus elicit the production of multiple different antibodies, which recognize and bind structurally distinct portions (i.e., epitopes) of the polypeptide. Furthermore, an antibody is capable of recognizing and binding antigenic determinants that are shared by polypeptides, which are otherwise structurally and/or functionally distinct from the claimed polypeptide to which it binds (e.g., a human protein's mouse homolog, or a different member of a functionally related family of proteins). Consequently, the disclosed relationship between an antibody that binds a polypeptide and the polypeptide is not exclusive, since either the claimed antibody or the claimed polypeptide can also be related to other polypeptides or antibodies, respectively, which are materially and chemically different

from the claimed inventions. Therefore, the inventions of Groups II and IV are patentably distinct products.

Searching both the inventions of Groups II and IV would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. A search of relevant sequence databases using the entire amino acid sequence of the polypeptide as query is necessary for the determination of the novelty and unobviousness of the polypeptide. However, such a search is not necessary, or sufficient to identify antibodies that bind the polypeptide, since antibodies that bind an epitope of the polypeptide may be known, even if the polypeptide is not (e.g., an anti-phosphotyrosine antibody binds a phosphotyrosine epitope, which is shared by numerous different proteins, and which would bind a novel tyrosine phosphorylated polypeptide). Accordingly, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, having to search both the inventions of Groups II and IV would constitute a serious burden.

Since the inventions of Groups II and IV are patentably distinct, and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

As noted above, the products of Group I are polynucleotides, which are composed of polymers of nucleotides, whereas the products of Group IV are antibodies, which are proteins composed of one or more polymers of amino acids. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, the claimed polynucleotide does not encode a polypeptide chain of the claimed antibody; and the claimed antibody cannot be encoded by the claimed polynucleotide. Therefore, the inventions of Group I and the inventions of Group IV are patentably distinct products.

Searching the inventions of both Groups I and IV would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. Therefore, having to search the inventions of both Groups I and IV would constitute a serious burden.

Since the inventions of Group I and the inventions of Group IV are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The products of Group III and the other claimed products are patentably distinct because the inventions of Group III are ribozymes, which are catalytic RNA molecules having the ability to catalyze the cleavage and formation of covalent bonds in RNA strands at specific sites. Ribozymes are materially, structurally, and/or functionally distinct from the other claimed products, which have been described in the paragraphs above.

Because of the these differences, the search necessary to examine claims directed to the inventions of Group III is not the same, nor is it coextensive with the search necessary to examine claims directed to any of the other products. Accordingly, a separate and different search would have to be performed to examine claims directed to any one of these groups of inventions. Therefore, the examination of more than one of the inventions would constitute a serious burden.

Since the inventions of Group III and any of the inventions of Groups I, II, and IV are patentably distinct, and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups V-VIII are unrelated, or are otherwise patentably distinct, each from the other, for the following reasons:

The inventions of Group V are "immunoassays", which are generally used to detect or quantify an antigen to which an antibody binds. In contrast, the inventions of Group VI are processes for identifying caspase-8 interacting proteins using a yeast-two-hybrid assay, the inventions of Group VII are processes of modulating caspase-8

activity and the inventions of Group VIII are processes for modulating TNF receptor- or Fas-mediated effects in a cell and/or modulating the cell's apoptosis.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, and different effects. See MPEP §§ 806.04 and 808.01. The instant specification does not appear to disclose that any of the inventions of Groups V-VIII are useable together. Therefore, because the inventions have different purposes, the inventions appear unrelated.

If not unrelated, the inventions of Groups V-VIII are patentably distinct, each from the others, for the following reasons:

Again, the inventions have different purposes or objectives. In addition, the inventions are materially different processes comprising different process steps. Because the inventions of the different groups have different purposes or objectives, they necessarily involve the measurement of different endpoints and the establishment of different correlations; and as such, the different inventions necessarily have different criteria for success. For these reasons, any of the inventions of Groups V-VIII are patentably distinct, each from the others.

Because any of the inventions of Groups V-VIII are distinct for these reasons, the search required to examine claims directed to any one of these inventions is not the same, nor is it coextensive with the search required to examine claims directed to any other. Furthermore, the inventions of Groups V-VIII have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter. Because different searches would have to be performed to examine claims directed to each of the inventions of Groups V-VIII, an examination of more than one would constitute a serious burden.

Since the inventions of Groups V-VIII have been shown to be patentably distinct, each from the others, and because the examination of more than one could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to patentably distinct species of the claimed invention, wherein said polypeptide that binds to caspase-8 is a polypeptide selected from the group consisting of (a) a polypeptide comprising the amino acid sequence of SEQ ID NO: 6 (b) a polypeptide comprising the amino acid sequence of SEQ ID NO: 7.

Each species of invention is patentably distinct from the others since each member of the genus of "polypeptides that binds to caspase-8" is distinct from the others; this is because each has a unique amino acid sequence that differs from the others.

Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, because the search of any one member of the genus of "polypeptides that binds to caspase-8" will not provide adequate information regarding any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one "polypeptide that binds to caspase-8" to which the claims of elected group of inventions will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species

of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D., whose telephone number is

(571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Primary Examiner
Art Unit 1643

slr
January 8, 2007